PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

Surrogate Markers for Sudden Cardiac Death in Patients With Diabetes Mellitus and End Stage Renal Disease

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Aim: Patients with type 2 diabetes mellitus (T2DM) and hemodialysis due to diabetic nephropathy exhibit a high risk for sudden cardiac death (SCD). Preliminary data suggest that beta-blocker treatment may reduce arrhythmias and mortality in this high-risk population. However, no results from large-scale clinical outcome trials with beta-blockers exist in this patient group and a broad, scientifically unapproved use of beta-blocker treatment may not be justified due to potential harmful side-effects such as AV-block or hypotension. In addition, we are lacking identified ECG surrogate parameters for SCD in this high-risk population and on the occurrence of arrhythmias in temporary relationship to hemodialysis sessions.

Therefore, the present study will identify surrogate parameters of SCD in hemodialysis patients with T2DM and in an interventional trial investigate the suppressive effect of beta-blockers on these identified ECG markers.

Brief Summary in Scientific Language

[---]*

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00006372**
- Date of Registration in DRKS: **2015/04/09**
- Date of Registration in Partner Registry or other Primary Registry: **2013/10/23**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT02001480 (ClinicalTrials.gov)**
- Sponsor-ID: **12-039 (RWTH Aachen University)**

Health condition or Problem studied

- Free text: **Diabetes Mellitus Type 2**
- Free text: **End Stage Renal Disease**
- ICD10: **E11 - Non-insulin-dependent diabetes mellitus**
- ICD10: **N18.5 - Chronic kidney disease, stage 5**

Interventions/Observational Groups

- Arm 1: **Device: 12 lead Holter**
- Arm 2: **Device: CGM Continuous Glucose Monitoring**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
-

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Single arm study**

- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Prevention**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- ECG surrogate markers compared to cardiac events; time frame: Analysis will be performed after last patient is out; Recruiting Period: October 2013 - April 2014 (6 months)/ Last patient out: April 2014/ Data cleaning, processing, analysis, study report: May 2014 - October 2014 (6 months)

Secondary Outcome

- Continuous glucose monitoring is performed to identify episodes of hypoglycaemia; time frame: Analysis will be done after last patient is out; Recruiting/active Period: October 2013 - April 2014 (6 months)/ Last patient out: April 2014/ Data cleaning, processing, analysis, study report: May 2014 - October 2014 (6 months)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- **regioMed-Kliniken GmbH, Coburg**
- **University Hospital Würzburg, Würzburg**
- **Department of Internal Medicine I University Hospital RWTH Aachen, Aachen**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2013/10/31**
- Target Sample Size: **60**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **[---]***

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- patients with diabetes mellitus type 2

- chronic hemodialysis at least since 3 months

- aged above 18 years

- written informed consent

- legally competent

Exclusion criteria

- intake of bets-blockker within the last four weeks

- pregnancy and breast feeding

- abuse of drugs and alcohol

- missing compliance

- life expectancy < 6 month

Addresses

- **Primary Sponsor**

  RWTH Aachen University

Primary Sponsor

RWTH Aachen University

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

- **Contact for Scientific Queries**

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E-mail: **nmarx at ukaachen.de**
URL: **[---]***

Sources of Monetary or Material Support

- **[---]***

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.

- Translation on version: 1

- Last processed date by ClinicalTrials.gov: 2014/07/16

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*